PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference I15500-PDG	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US2005/010534	International filing date *(day/month/year)* 29.03.2005	Priority date *(day/month/year)* 31.03.2004
International Patent Classification (IPC) or national classification and IPC INV. A61M25/00		
Applicant COOK INCORPORATED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 9 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15.11.2005	21.07.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Mausser, T Telephone No. +49 89 2399-2355

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2005/010534

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-15	as originally filed

Claims, Numbers

1-26	received on 15.11.2005 with letter of 11.11.2005

Drawings, Sheets

1/4-4/4	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-16,18-21,23-26
	No:	Claims	1,17,22
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-26
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V.

1 Reference is made to the following documents:
D1 : US 5 797 878 A (BLEAM ET AL) 25 August 1998 (1998-08-25)
D2 : US 2003/139762 A1 (LEE JEONG S) 24 July 2003 (2003-07-24)

2 INDEPENDENT CLAIMS 1, 17 and 22

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses on figures 5 to 8 a balloon with rounded (not abrupt) transition zones without a kink, comprising a radius. See especially figure 6 at angle alpha.
The applicant argued rightly that there is no explicit statement of size concerning the radius of the taper to neck transition or the radius of the length to taper transition in D1. However, lack of novelty seems apparent from what is stated in the document: Column 6, lines 32 to 41 indicates a taper length of between 3mm and 9mm. Considering the proportions in figure 6 the person skilled in the art could directly and unambiguously conclude that the radius at angle alpha in figure 6 must at least be greater than 0.127 mm. It must be kept in mind that a radius of only 0.127 mm or less means a rather sharp edge in practice (or in a drawing like figure 6).
As for novelty of claims 1, 17 and 22 the attention is drawn as well to D2. See especially Figure 1, para 0022 and 0023.

DEPENDENT CLAIMS 2-16, 18-21, 23-26
The combination of the features of dependent claims 2-16, 18-21 and 23-26 consists essentially in the selection of ranges. Such a selection can only be regarded as inventive, if the range presents unexpected effects or properties in relation to the rest of the range. However, no such effects or properties are indicated in the application. Hence, no inventive step is present in the subject-matter of claims 2-16, 18-21 and 23-26.

Further comments:

1.) The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2.) It would have been appropriate to draft the independent claim in the two-part form, whereby the features known from D1 should have been placed in the preamble.

3.) D1 should have been mentioned in the description.

What is claimed is:

1. A dilation catheter comprising:

an elongate catheter body with at least one lumen; and

a medical balloon disposed about a portion of the elongate catheter body in fluid communication with the lumen, the medical balloon comprising:

a proximal taper region and a distal taper region;

a balloon cylindrical working length intermediate the proximal region and the distal region;

a proximal taper-to-neck transition and a proximal working length-to-taper transition that define the proximal region;

a distal taper-to-neck-transition and a distal working length-to-taper transition that define the distal region;

wherein at least one transition of the proximal taper-to-neck transition, the proximal working length-to-taper transition, the distal taper-to-neck transition, and the distal working length-to-taper transition comprises a radius greater than 0.127 mm before inflation.

2. The dilation catheter of claim 1, where the radius is from:

0.97 to 3.3 mm when the balloon has a diameter of about 3 mm,

1.8104.7mm when the balloon has a diameter of about 4 mm,

2.4 to 6.4 mm when the balloon has a diameter of about 5 mm,

3.5 to 8.3 mm when the balloon has a diameter of about 6 mm,

4.8 to 10.2 mm when the balloon has a diameter of about 7 mm,

6.2 to 11,4 mm when the balloon has a diameter of about 8 mm,

6.7 to 13.3 mm when the balloon has a diameter of about 9 mm,

8.1 to 15.2 mm when the balloon has a diameter of about 10 mm,

9.1 to 17.1 mm when the balloon has a diameter of about 11mm,

9.9 to 19.1 mm when the balloon has a diameter of about 12mm,
11.2 to 22.9 mm when the balloon has a diameter of about 14 mm, and
13.3 to 25.4 mm when the balloon has a diameter of about 15mm.

3. The dilation catheter of claim 1, where the radius is from:
1.3 to 3.3mm when the balloon has a diameter of about 3 mm,
2.5 to 4.7 mm when the balloon has a diameter of about 4 mm,
3.2 to 6.4 mm when the balloon has a diameter of about 5 mm,
4.7 to 8.3 mm when the balloon has a diameter of about 6 mm,
6.4 to 10.2 mm when the balloon has a diameter of about 7 mm,
8.3 to 11.4 mm when the balloon has a diameter of about 8 mm,
8.9 to 13.3 mm when the balloon has a diameter of about 9 mm,
10.8 to 15.2 mm when the balloon has a diameter of about 10 mm,
12.1 to 17.1 mm when the balloon has a diameter of about 11 mm,
13.3 to 19.1 mm when the balloon has a diameter of about 12 mm,
14.9 to 22.9 mm when the balloon has a diameter of about 4 mm, and
17.8 to 25.4 mm when the balloon has a diameter of about 15 mm.

4. The dilation catheter of claim 1, where the radius is:
about 2.5 mm when the balloon has a diameter of about 3 mm,
about 3.2 mm when the balloon has a diameter of about 4 mm,
about 4.7 mm when the balloon has a diameter of about 5 mm,
about 6.4 mm when the balloon has a diameter of about 6 mm,
about 8.3 mm when the balloon has a diameter of about 7 mm,
about 8.9 mm when the balloon has a diameter of about 8 mm,

about 10.8 mm when the balloon has a diameter of about 9 mm,
about 12.1 mm when the balloon has a diameter of about 10 mm,
about 13.3 mm when the balloon has a diameter of about 11 mm,
about 14.9 mm when the balloon has a diameter of about 12 mm,
about 17.8 mm when the balloon has a diameter of about 14 mm, and
about 19.1 mm when the balloon has a diameter of about 15 mm.

5. The dilation catheter of claim 1, where the radius is from about 1.9 mm to about 13 mm.

6. The dilation catheter of claim 1, where the radius is from about 4 mm to about 13 mm.

7. The dilation catheter of claim 1, where the radius is from about 7 mm to about 13mm.

8. The dilation catheter of claim 1, where the radius is at least 1.9 mm.

9. The dilation catheter of claim 1, where the radius is at least 4 mm.

10. The dilation catheter of claim 1, where the radius is at least 7 mm.

11. The dilation catheter of claim 1, where the proximal taper-to-neck radius is substantially equal to the proximal working length-to-taper radius.

12. The dilation catheter of claim 1, where the distal taper-to-neck radius is substantially equal to the distal working length-to-taper radius.

13. The dilation catheter of claim 1, where the proximal taper-to-neck radius, the proximal working length-to-taper radius, the distal taper-to-neck radius, and the distal working length-to-taper radius are substantially equal.

14. The dilation catheter of claim 1, where the proximal taper-to-neck radius and the proximal working length-to-taper radius are substantially equal to each other, but different from the distal taper-to-neck radius and the distal working length-to-taper radius, which are substantially equal to each other.

15. The dilation catheter of claim 1, where the proximal working length-to-taper radius and the proximal taper-to-neck radius are different.

16. The dilation catheter of claim 1, where the proximal working length-to-taper radius, the proximal taper-to-neck radius, the distal working length-to-taper radius, and the distal taper-to-neck radius are all different.

17. A method of making a dilation catheter, comprising:

fixing a balloon to an elongate catheter body with at least one lumen in fluid communication with the balloon, the balloon being disposed about a portion of the catheter tube, the medical balloon comprising:

a proximal taper region and a distal taper region;

a balloon cylindrical working length intermediate the proximal region and the distal region;

a proximal taper-to-neck transition and a proximal working length-to-taper transition that define the proximal region;

a distal taper-to-neck-transition and a distal working length-to-taper transition that define the distal region;

wherein at least one transition of the proximal taper-to-neck transition, the proximal working length-to-taper transition, the distal taper-to-neck transition, and the distal working length-to-taper transition comprises a radius greater than 0.127 mm before inflation.

18. The method of claim 17, where the radius is from:
0.97 to 3.3 mm when the balloon has a diameter of about 3 mm,
1.8 to 4.7mm when the balloon has a diameter of about 4mm,
2.4 to 6.4 mm when the balloon has a diameter of about 5 mm,
3.5 to 6.3 mm when the balloon has a diameter of about 6 mm,
4.8 to 10.2 mm when the balloon has a diameter of about 7 mm,
6.2 to 11.4 mm when the balloon has a diameter of about 8 mm,
6.7 to 13.3 mm when the balloon has a diameter of about 9 mm,
8.1 to 15.2mm when the balloon has a diameter of about 10mm,
9.1 to 17.1 mm when the balloon has a diameter of about 11 mm,
9.9 to 19.1 mm when the balloon has a diameter of about 12 mm,
11.2 to 22.9 mm when the balloon has a diameter of about 14 mm, and
13.3 to 25.4 mm when the balloon has a diameter of about 15 mm.

19. The method of claim 17, where the radius is from:
1.3 to 3.3 mm when the balloon has a diameter of about 3 mm,
2.5 to 4.7 mm when the balloon has a diameter of about 4 mm,
3.2 to 6.4 mm when the balloon has a diameter of about 5 mm,
4.7 to 8.3 mm when the balloon has a diameter of about 6 mm,
6.4 to 10.2 mm when the balloon has a diameter of about 7 mm,
8.3 to 11.4 mm when the balloon has a diameter of about 8 mm,
8.9 to 13.3 mm when the balloon has a diameter of about 9 mm,

10.8 to 15.2 mm when the balloon has a diameter of about 10mm,
12.1 to 17.1 mm when the balloon has a diameter of about 11 mm,
13.3 to 19.1 mm when the balloon has a diameter of about 12 mm,
14.9 to 22.9 mm when the balloon has a diameter of about 14 mm, and
17.8 to 25.4 mm when the balloon has a diameter of about 15 mm.

20. The method of claim 17, where the radius is:
about 2.5 mm when the balloon has a diameter of about 3 mm,
about 3.2mm when the balloon has a diameter of about 4mm,
about 4.7 mm when the balloon has a diameter of about 5 mm,
about 6.4mm when the balloon has a diameter of about 6mm,
about 8.3mm when the balloon has a diameter of about 7mm,
about 8.9mm when the balloon has a diameter of about 8mm,
about 10.8 mm when the balloon has a diameter of about 9 mm,
about 12.1 mm when the balloon has a diameter of about 10mm,
about 13.3 mm when the balloon has a diameter of about 11 mm,
about 14.9 mm when the balloon has a diameter of about 12mm,
about 17.8 mm when the balloon has a diameter of about 14mm, and
about 19.1 mm when the balloon has a diameter of about 15 mm.

21. The method of claim 17, where the radius is at least 1.9 mm.

22. A method of reducing the force required to remove a dilation catheter from a conduit, comprising:

(a) inserting the dilation catheter through the conduit, so a medical balloon disposed on the catheter emerges from the conduit, wherein the dilation catheter includes an elongate catheter body, the medical balloon comprising:

a proximal taper region and a distal taper region;

a balloon cylindrical working length intermediate the proximal region and the distal region;

a proximal taper-to-neck transition and a proximal working length-to-taper transition that define the proximal region;

a distal taper-to-neck-transition and a distal working length-to-taper transition that define the distal region;

wherein at least one transition of the proximal taper-to-neck transition, the proximal working length-to-taper transition, the distal taper-to-neck transition, and the distal working length-to-taper transition comprises a radius greater than 0.127 mm before inflation;

(b) inflating the balloon by providing a fluid to a catheter lumen in fluid communication with the balloon;

(c) deflating the balloon; and

(d) applying a force to the dilation catheter, so the balloon is removed from the conduit.

23. The method of claim 22, where the radius is from:

0.97 to 3.3 mm when the balloon has a diameter of about 3 mm,

1.8 to 4.7 mm when the balloon has a diameter of about 4 mm,

2.4 to 6.4 mm when the balloon has a diameter of about 5 mm,

3.5 to 8.3 mm when the balloon has a diameter of about 6 mm,

4.8 to 10.2 mm when the balloon has a diameter of about 7 mm,

6.2 to 11.4 mm when the balloon has a diameter of about 8 mm,

6.7 to 13.3 mm when the balloon has a diameter of about 9 mm,

8.1 to 15.2 mm when the balloon has a diameter of about 10mm,
9.1 to 17.1 mm when the balloon has a diameter of about 11mm,
9.9 to 19.1 mm when the balloon has a diameter of about 12 mm,
11.2 to 22.9 mm when the balloon has a diameter of about 14 mm, and
13.3 to 25.4 mm when the balloon has a diameter of about 15mm.

24. The method of claim 22, where the radius is from:
1.3 to 3.3 mm when the balloon has a diameter of about 3 mm,
2.5 to 4.7 mm when the balloon has a diameter of about 4 mm,
3.2 to 6.4 mm when the balloon has a diameter of about 5 mm,
4.7 to 8.3 mm when the balloon has a diameter of about 6 mm,
6.4 to 10.2 mm when the balloon has a diameter of about 7 mm,
8.3 to 11.4 mm when the balloon has a diameter of about 8 mm,
8.9 to 13.3 mm when the balloon has a diameter of about 9 mm,
10.8 to 15.2 mm when the balloon has a diameter of about 10mm,
12.1 to 17.1 mm when the balloon has a diameter of about 11 mm,
13.3 to 19.1 mm when the balloon has a diameter of about 12mm,
14.9 to 22.9 mm when the balloon has a diameter of about 14mm, and
17.8 to 25.4 mm when the balloon has a diameter of about 15mm.

25. The method of claim 22, where the radius is:
about 2.5 mm when the balloon has a diameter of about 3 mm,
about 3.2mm when the balloon has a diameter of about 4mm,

about 4.7 mm when the balloon has a diameter of about 5 mm,
about 6.4 mm when the balloon has a diameter of about 6 mm,
about 8.3 mm when the balloon has a diameter of about 7 mm,
about 8.9 mm when the balloon has a diameter of about 8 mm,
about 10.8 mm when the balloon has a diameter of about 9 mm,
about 12.1 mm when the balloon has a diameter of about 10mm,
about 13.3 mm when the balloon has a diameter of about 11 mm,
about 14.9 mm when the balloon has a diameter of about 12mm,
about 17.8 mm when the balloon has a diameter of about 14mm, and
about 19.1 mm when the balloon has a diameter of about 15mm.

26. The method of claim 22, where the radius is at least 1.9 mm.